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09/991,293	11/16/2001	Laura C. Singleton	NEU-41	3865

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species H2-Gly-His-Lys-NH2 in the reply filed on 1-16-04 is acknowledged.

Claims 32 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-16-04.

Newly submitted claims 36, 43-45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 36 and 43 are drawn to a medical device. The claims drawn to the device, even though utilizes the peptides, would be a burdensome search. a search for the peptide would not necessarily lead to the device. Rather the search would have be limited to the medical device.

The inventions of Claim 44 and 45 are method of enhancing stability of an aqueous solution. Inventions of claim 44 and 45 and the invention of claim 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of claim 44 can be practiced with materially different stabilizer's such as sugars or other stabilizing carbohydrates known in the art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 16, 43-45 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 4, 8, 10, 16, and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 and 8 recite a specific peptide of the formula I. It is unclear from the formula how R1 and R2 are related to the peptide. The use of the symbol > implies that R1 and R2 are either greater than A1. It is believed that the symbol is used to indicate that R1 and R2 are bonded to A1. If this is the case, Applicants are requested to amend the claim to specifically recite that R1 and R2 are bonded to A1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 5-7, 9, 11, 13-15, 25-30, 33-34, 37, and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession (emphasis added), as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of

California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to formulation comprising a peptide complexed with copper ion and a second additive such as a basic amino acid or non-ionic emulsifier. The generic statements of a peptide complexed with a copper ion does not provide sufficient written description since the claims do not describe a single structural feature of the peptide. The presence of a copper ion does not provide sufficient written description of the peptide since the copper is only complexed to the peptide. The claims do not state that it be complexed to a specific peptide or amino acid. The specification does provide examples of what qualify as compounds of the claimed invention. However, these are limited to small peptides that contain a histidine residue (see page 4 of the specification). The specific peptides disclosed are further limiting since they are only drawn to tri-peptides that have a His-Lys residue as the second and third residue.

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As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 11 is a broad generic with respect all possible peptides encompassed by the claims. The possible structural variations are limitless to any length of peptide that contains either natural or non-naturally occurring amino acid. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims do not recite any functional characteristics and thus one cannot even use any functional limitation to define the structure of the desired peptide. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of any peptides that are longer than three amino acids in length or have a His-Lys residue in the second and third position of the peptide. The specification is limited to the above mentioned peptides that have a common core. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-27, 30, 31, 33, 35, 37-38, 40, and 42 are rejected under 35 U.S.C. 102(a) as being anticipated by Lookout.

The claims are drawn to a peptide copper complex with a basic amino acid and non-ionic emulsifier.

Lookout reference discloses that “Neutrogena has unveiled the Neutrogena Visibly Firm Night Cream, a moisturizing night cream that replenishes the copper found naturally in the body (see abstract). The reference discloses that the cream is sold in an overboxed 1.7oz glass jar with copper colored twist off cap for \$19.99. Note that Dermastore reference disclose that Neutrogena “Visibly Firm Face” lotion is sold in a 1.7 oz bottle and contains PEG-100 Sterate as the non-ionic emulsifier and arginine as the basic amino acid. Note that the application of the of web page reference is applicable, even though it was not published prior to Applicants claimed invention because references cited to show a universal fact need not be available as prior art before applicant’s filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. The web page reference was cited to illustrate that characteristics and properties disclosed by the Lookout reference.

5. Claims 7-26 are rejected under 35 U.S.C. 102(b) as being anticipated by PR Newswire.

The claims are drawn to a peptide copper complex with non-ionic emulsifier.

The PR Newswire reference discloses that the product Procyte corporation markets a product known as Neova Mattifying Serum with copper peptide complex (see abstract). The product is effective in absorbing oil and keeping the skin shine-free and comfortably moisturized (see abstract). Neova Mattifying Serum is known in the art to contain non-ionic emulsifier such as polyacrylamide (see web page from Derma Doctor). Note that the application of the of web page reference is applicable, even though it was not published prior to Applicants claimed invention because references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. The webpage reference was cited to illustrate that characteristics and properties disclosed by the PR Newswire reference.

6. Claims 1-31 and 33-35 and 38-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Patt (US2003/0148927).

The claims are drawn to a peptide copper complex with a basic amino acid and non-ionic emulsifier.

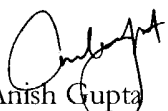
Patt teaches compositions comprising an aqueous solution of at least one peptide copper complex (see abstract). The reference discloses that the tripeptide is glycyl-L-histidyl-L-lysine:copper (II) (see claim 21). The reference discloses that the composition can contain a basic amino acid such as lysine or arginine (see claim 26-27). The reference states that the solution is in the form of cream, gel, emulsion, or microemulsion (see claim 30) and contains a preservative such as benzyl alcohol (see claims 8-9). The reference also discloses that propylene glycol can be used in the

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aqueous solution which meets the non-ionic emulsifier limitation (see claim 10). Thus, the reference anticipates the claimed invention.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 11/10/09
Anish Gupta
Patent Examiner